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November 15, 1999

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, room 1061
Rockville, MD 20852

RE: Draft Guidance for Industry
ANDAs: Blend Uniformity Analysis
Docket No. 99D-2635

Dear Sir or Madam:

Perrigo Company respectfully submits these comments in response to the Food and Drug Administration's "Draft Guidance for Industry; ANDAs: Blend Uniformity Analysis, Docket No. 99D-2635.

General Comments:

Perrigo Company does not support the policy of conducting routine in-process blend uniformity testing for the following reasons:

1. FDA has not presented the scientific basis for this requirement. There is no body of evidence to show that employing this test will add more assurance for content uniformity of the dosage form.

2. Because of physical and statistical problems with analytical sampling and/or post-blend processing (i.e., transfers, packaging) blend uniformity testing is rarely predictive of the finished dosage form uniformity (suspension, ointment, or tablet).

3. There are no industry-accepted standards for sampling equipment and/or techniques. This could lead to wrong types of equipment being used and erroneous results.

4. Content Uniformity testing meets the requirements in 21 CFR 211.110(a)(3), which assures "Adequacy of mixing to assure uniformity and homogeneity".

Item for Clarification:

Perrigo Company discussed the removal of Blend Uniformity testing with the FDA for a previously approved ANDA. Perrigo asked if upon validation of the product, a supplement would need to be submitted for the removal of this test. FDA stated that this issue needed to be brought to the attention of the field office and a supplement was not necessary. However, the draft guidance states on page 3, "A supplement requesting deletion of BUA testing...". Perrigo Company requests clarification from the FDA on the actual steps needed to delete the requirement for Blend Uniformity Analysis Testing.

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Conclusion:

Perrigo Company believes that blend uniformity is sufficiently analyzed at the process validation stage. Upon acceptable data, this testing should be eliminated, as the uniformity of the drug product will be monitored by Uniformity of Dosage testing at the final product stage.

Perrigo Company appreciates the opportunity to submit these comments. If you have any questions, please feel free to call me at 616-673-9745.

Sincerely,

Brian Schuster for Perrigo Company
Manager, ANDA Submissions

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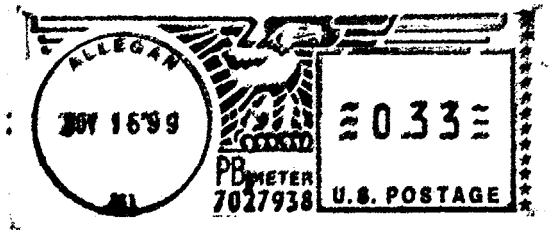

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